K031135

JUN - 2 2003

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: Lorraine Piestrak
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: April 8, 2003

Name of Product: Glucose Flex® reagent cartridge (GLUC)

FDA Classification Name: Glucose Test System

Predicate Device: Dimension® Glucose Method (K860021)

Device Description:

Intended Use: The Glucose Flex® reagent cartridge (GLUC) for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of glucose in human serum, plasma, urine, and cerebrospinal fluid.

Comparison to Predicate Device:

Item	GLUC Flex® reagent cartridge	GLU Flex® reagent cartridge
Sample Type	Serum, plasma, urine, and cerebrospinal fluid	Serum, plasma, urine, and cerebrospinal fluid
Technology	Enzymatic: Hexokinase– glucose-6 phosphate dehydrogenase	Enzymatic: Hexokinase– glucose-6-phosphate dehydrogenase
Detection	Bichromatic endpoint measurement- NADH (340 & 383 nm)	Bichromatic endpoint measurement- NADPH (340 & 383 nm)
Reaction Time	120 seconds	180 seconds
Reagents	Liquid	Tablets

Comments on Substantial Equivalence:
Split sample comparison between the GLUC Flex® reagent cartridge on the Dimension® clinical chemistry system and the GLU Flex® reagent cartridge also on the Dimension® clinical chemistry system gave the following correlation statistics, when tested with clinical patient samples:

Sample Type	Slope	Intercept	Correlation Coefficient	n
Serum/Plasma	1.01	0.01	0.999	162
Urine	1.01	-1.05	1.000	64
Cerebrospinal Fluid	1.00	-0.54	1.000	70

Conclusion: The Glucose Flex® reagent cartridge (GLUC) is substantially equivalent in principle and performance to the Glucose Flex® reagent cartridge (GLU) assay based on the split sample comparison discussed above.

Lorraine Piestrak
Regulatory Affairs and Compliance Manager
Date: April 8, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 2 2003

Ms. Lorraine Piestrak
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: k031135
Trade/Device Name: Glucose Flex® reagent cartridge (GLUC)
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CFR
Dated: April 8, 2003
Received: April 9, 2003

Dear Ms. Piestrak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

Device Name: Glucose Flex® reagent cartridge (GLUC)

Indications for Use:

The Glucose Flex® reagent cartridge for the Dimension® clinical chemistry system is an *in vitro* diagnostic device intended to quantitatively measure glucose in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K031135

Lorraine Piestrak

Lorraine Piestrak
Regulatory Affairs and
Compliance Manager

April 8, 2003

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)